This is a combined synopsis/solicitation for commercial items prepared in accordance with the Federal Acquisition Regulation (FAR) format in Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; proposals are being requested and a written solicitation will not be issued. This solicitation is being issued in conjunction with FAR Part 13.106. The solicitation number is 17-223-SOL-00061. This solicitation is issued as a Request for Quote (RFQ).

The solicitation document and incorporated provisions and clauses in effect through the Federal Acquisition Circular 2005-94 and 2005-95, dated January 19, 2017.

The appropriate NAICS code for this acquisition is 334516- Analytical Laboratory Instrument Manufacturing; Small Business Size Standard is 1,000 employees. This requirement is setaside 100% for small business.

Schedule of Supplies or Services and Prices/Costs (inclusive of delivery, installation,

and on-site training
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CLIN	Description	Qty	Unit	Unit Price	Total Price
0001	Compact Feeder and components	1	Ea		

## **Statement of Work**

# Background/Introduction

As one of the manufacturing approaches listed in the Food and Drug Administration (FDA) strategic plan for advancing regulatory science (2011), continuous manufacturing has been discussed in recent pharmaceutical conferences and holds great promise for the future of pharmaceutical manufacturing. In April 2016, pharmaceutical advanced manufacturing has been identified as the nation's priority technology areas by the White House. Given the rapid development of continuous manufacturing in the pharmaceutical industry, there is a need to establish a laboratory-scale continuous manufacturing line in the Division of Product Quality Research (DPQR) to upgrade its research infrastructure to meet the advanced manufacturing regulatory research need. Since feeding is the first step for any continuous manufacturing processes, we propose to purchase a feeding system that enables to feed various types of pharmaceutical ingredients.

### Scope

DPQR requires a compact feeder to support the Center for Drug Evaluation and Research (CDER) continuous manufacturing initiatives. This feeder will serve as a key component in establishing a continuous manufacturing pharmaceutical real-time process monitoring and control system.

# **General Requirement**

The components and/or equipment shall be a newly manufactured, not used and refurbished, or previously used for demonstration.

#### **Technical Requirements**

At a minimum, the compact feeder shall meet the following requirement:

- Product contact metal parts shall be stainless steel with pharmaceutical grade metal finish, non metal product contact parts are made of FDA compliant materials. <a href="http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryStatusFood">http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RegulatoryStatusFood</a> ContactMaterial/ucm120771.htm
- Hopper volume should be no more than 12L.

- Capable of feeding with the rate between 1-30 L/hr.
- Interchangeable gearboxes to ensure feeding accuracy and consistency at lower and higher feed rates.
- Shall include fine and coarse concave twin-screws.
- Additional fine and coarse auger twin screws may be provided.
- The interchangeable feeding tools shall be capable of gravimetric feeding of free flowing to very poorly flowing powders.
- Shall have compact horizontal design.
- Shall have easy access to parts for cleaning.
- Shall be equipped with control system to enable operator control at the interface.
- Shall include control system that assure feeding accuracy during re-fill with a refill stabilization time not more than 90 seconds.
- Shall include operational software for download on customer supplied PC.
- Shall be equipped with data recorder to save feeder process data to PC, connect with feeder controllers, use Ethernet or serial physical connection for interfacing.
- Shall be equipped with sampler device for the evaluation and validation of the mass flow performance in terms of repeatability and deviation from set points.
- Full system software and peripheral installation.
- Shall include surface roughness test.
- shall include weight test certificate.

# Installation, Training, and Additional System Requirements

- The instrument shall be warranted for parts and labor for 12 months from date of installation acceptance. All warranty work shall be performed on-site at FDA/CDER, i.e., returning the equipment to the manufacturer is unacceptable.
- The system shall be delivered with all components, accessories, start-up supplies required for installation and start-up., i.e., a turn-key solution.
- The Contractor shall provide on-site (Government-site) operator familiarization training of the system upon completion of installation. Such familiarization shall include system operations, optimization, hardware, software, and basic preventive maintenance procedures.
- The Contractor shall include all parts, travel, and labor to complete installation. Installation shall be performed and completed during normal duty hours (Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time).

Contract Type: Commercial Item-Firm Fixed Price

**Period of Performance:** FOB Destination. Delivery, installation, and on-site training shall be not later than ninety (90) calendar days after receipt of contract award.

Delivery Address:
Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
WO Building 62 Loading Dock
Silver Spring, MD 20993
POC (Will be provided at time of award)

Repairs and Preventative Maintenance visits shall not be scheduled during Federal Holidays or Federal Closures as determined by Executive Orders or opm.gov. Federal holidays are as follows:

New Year's Day Birthday of Martin Luther King, Jr. Washington's Birthday Memorial Day Independence Day Labor Day Columbus Day Veteran's Day Thanksgiving Day Christmas Day

The provision at FAR 52.212-1 Instructions to Offerors - Commercial Items (JAN 2017) applies to this solicitation. The following addenda apply:

It is the offeror's responsibility to monitor FedBizOpps for information relevant to this solicitation, e.g., questions and answers, amendments, etc.

All questions shall be submitted to Regina Williams via email at Regina.williams@fda.hhs.gov. Questions are due no later than April 17, 2017, 12:00 p.m. Central Time. No phone calls will be accepted.

Paragraph (b). The government is not responsible for locating or securing any information, which is not identified in the quote.

Paragraph (b)(4). To ensure information is available, offerors shall furnish as part of their proposal all descriptive material necessary for the government to conclusively determine that the proposed technical solution meets or exceeds the Government's requirements. Offerors shall address each technical requirement stated above to demonstrate that the proposal meets the technical requirements. In addition to identifying manufacturer, make, and model of offered products it is incumbent of offerors that they unequivocally demonstrate that offered products and post-warranty maintenance services meet the requirements herein through the submission of technical specifications, descriptive material, scientific literature, brochures, scientific publications where proposed solution has been used for same or similar purposes, and other information which demonstrates the acceptability of the offered supplies/services.

The price proposed shall represent the offeror's response to the schedule of supplies/services above. The post warranty option periods will not be funded at time of award. If exercised, funding will be obligated individually each year for the option period exercised via contract modification.

Include the firm's DUNS number with quote.

The government is not responsible for locating or securing any information, which is not identified in the proposal, however the Government reserves the right to obtain information for use in the evaluation from any and all sources including sources outside of the Government.

Paragraph (k). To be considered for award an offeror shall be registered and active in SAM by the date and time set forth for receipt of quotes/proposals.

The provision at 52.212-2 Evaluation-Commercial Items (OCT 2014) is applicable to this solicitation.

The Government will award a contract resulting from the RFQ to the responsible party whose quote conforming to the RFQ offers the best value to the Government, price and other factors considered. For the purposes of this RFQ best value is defined as lowest price technically acceptable.

Proposals will first be ranked from lowest to highest total price. The lowest price proposal shall then be evaluated regarding technical acceptability. If determined technically acceptable and the price is reasonable an award will be made to that offeror. If however the lowest priced offer is determined technically unacceptable the next lowest price proposal shall be evaluated regarding technical acceptability. This process will continue until a technically acceptable proposal is found.

(c) A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

The Provision at FAR 52.212-3, Offeror Representations and Certifications-Commercial Items (JAN 2017), applies to this acquisition. The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) website located at https://www.sam.gov/portal. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (u) of this provision.

The clause at 52.212-4, Contract Terms and Conditions-Commercial Items (JAN 2017), applies to this acquisition. The following addenda apply:

The supplies and/or services delivered hereunder shall be inspected and accepted at destination by the Technical Representative (TR) specified at award. If the supplies or services are acceptable, the TR shall promptly forward a report of inspection and acceptance to the paying office. If the supplies or services are not acceptable, the TR shall document the nonconforming items/services and immediately notify the Contracting Officer.

The following FAR and HHSAR provisions and clauses, incorporated by reference, apply to this acquisition and can be obtained at <a href="https://www.acquisition.gov/far/">https://www.acquisition.gov/far/</a> and <a href="https://farsite.hill.af.mil/VFHHSAR1.htm">https://farsite.hill.af.mil/VFHHSAR1.htm</a>.

FAR Clause

52.232-40 Providing Accelerated Payment to Small Business Subcontractors (DEC 2013)

HHSAR Clause

352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)

352.223-70 Safety and Health (DEC 2015)

The following Technical Representative (TR) will represent the Government for the purpose of this contract: (To be provided upon contract award)

Name:

Email Address:

Phone:

The TR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the contract; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The contact information for the Contracting Officer:

Name:

Regina Williams

Email Address:

regina.williams@fda.hhs.gov

Phone:

870.543.7012

Mailing Address:

DHHS/FDA/OAGS/DAP Jefferson Laboratories 3900 NCTR Road Bldg. 50, Room 419 Jefferson, AR 72079

## **Payments**

Payment will be made upon Government acceptance of the system (inclusive of delivery, installation, and training).

Invoice Submission

The contractor shall submit one (1) original copy of the invoice to the address specified below:

FDA/OO/OFBA/OFO/OFS

Attn: Division of Payment Services

3900 NCTR Road

Building 50, 6th Floor Suite 616, HFT-324

Jefferson, AR 72079

E-mail: nctrinvoices@fda.hhs.gov

One copy to the Technical Representative (TR) or other program center/office designee, identified above, clearly marked "courtesy copy only":

- \*\* Acceptable methods of delivery include: mail, hand delivery, or e-mail.
- B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer-Central Contractor Registration) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:
- (I) Name and address of the contractor;
- (ii) Invoice date and invoice number;
- (iii) Purchase order/award number;
- (iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:
- (a) period of performance for which costs are claimed;
- (b) itemized travel costs, including origin and destination;
- (c) any other supporting information necessary to clarify questionable expenditures;
- (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;
- (vi) Terms of any discount for prompt payment offered;
- (vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment);
- (viii) Name, title, and phone number of person to notify in event of defective invoice;
- (ix) Taxpayer identification number (TIN);
- (x) Electronic funds transfer (EFT) banking information, including routing transit number of the financial institution receiving payment and the number of the account into which funds are to be deposited;
- (xi) Name and telephone number of the FDA Contracting Officer Representative (COR) or other program center/office point of contact, as referenced on the purchase order;
- (xii) Any other information or documentation required by the purchase order/award.
- (Xiii) Contractor is not required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
- (a) list of all invoices submitted to date under the subject award, including the following:

- (1) invoice number, amount, & date submitted
- (2) corresponding payment amount & date received
- (b) total amount of all payments received to date under the subject contract or order
- (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance
- C. An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xii) of this clause must be included in the electronic invoices. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.
- D. Questions relating to when payment will be received should be directed to the FDA payment office at the email below or at (870) 543-7446 or (870) 543-7042. nctrinvoices@fda.hhs.gov.
- 52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders-Commercial Items (Jan 2017)
- (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
- (1) <u>52.203-19</u>, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (2) <u>52.209-10</u>, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).
- (3) <u>52.233-3</u>, Protest After Award (Aug 1996) (<u>31 U.S.C. 3553</u>).
- (4) <u>52.233-4</u>, Applicable Law for Breach of Contract Claim (Oct 2004)(Public Laws 108-77 and 108-78 (<u>19 U.S.C. 3805 note</u>)).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- \_\_ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).
- $\underline{\hspace{0.5cm}}$  (2)  $\underline{52.203-13}$ , Contractor Code of Business Ethics and Conduct (Oct 2015) ( $\underline{41~U.S.C.}$   $\underline{3509}$ )).
- (3) <u>52.203-15</u>, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- $\underline{X}$  (4)  $\underline{52.204-10}$ , Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2016) (Pub. L. 109-282) (31 U.S.C. 6101 note).
- \_\_ (5) [Reserved].
- \_\_ (6) <u>52.204-14</u>, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- \_\_ (7) <u>52.204-15</u>, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
- $\underline{X}$  (8)  $\underline{52.209-6}$ , Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note).
- \_\_\_ (9) <u>52.209-9</u>, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).
- \_\_ (10) [Reserved].
- \_\_\_ (11)(i) <u>52.219-3</u>, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).
- \_\_\_ (ii) Alternate I (Nov 2011) of <u>52.219-3</u>.
- \_\_ (12)(i) <u>52.219-4</u>, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (<u>15 U.S.C. 657a</u>).

- (ii) Alternate I (Jan 2011) of 52.219-4. (13) [Reserved]  $\underline{X}$  (14)(i)  $\underline{52.219-6}$ , Notice of Total Small Business Set-Aside (Nov 2011) ( $\underline{15}$  U.S.C. 644). \_\_ (ii) Alternate I (Nov 2011). (iii) Alternate II (Nov 2011). \_\_ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644). \_\_ (ii) Alternate I (Oct 1995) of <u>52.219-7</u>. \_\_ (iii) Alternate II (Mar 2004) of 52.219-7. (16) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)).\_\_ (17)(i) 52.219-9, Small Business Subcontracting Plan (Jan 2017) (15 U.S.C. 637(d)(4)). \_\_ (ii) Alternate I (Nov 2016) of <u>52.219-9</u>. (iii) Alternate II (Nov 2016) of <u>52.219-9</u>. \_\_ (iv) Alternate III (Nov 2016) of 52.219-9. \_\_ (v) Alternate IV (Nov 2016) of <u>52.219-9</u>. \_\_ (18) <u>52.219-13</u>, Notice of Set-Aside of Orders (Nov 2011) (<u>15</u> U.S.C. 644(r)). (19) <u>52.219-14</u>, Limitations on Subcontracting (Jan 2017) (<u>15</u> U.S.C. 637(a)(14)). (20) 52.219-16, Liquidated Damages-Subcon-tracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)). (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657 f). X (22) 52.219-28, Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C. 632(a)(2)). (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (15 U.S.C. 637(m)). (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Dec 2015) (15 U.S.C. 637(m)). <u>X</u> (25) <u>52.222-3</u>, Convict Labor (June 2003) (E.O. 11755). X (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Oct 2016) (E.O. 13126). X (27) 52.222-21, Prohibition of Segregated Facilities (Apr 2015). <u>X</u> (28) <u>52.222-26</u>, Equal Opportunity (Sept 2016) (E.O. 11246). (29) <u>52.222-35</u>, Equal Opportunity for Veterans (Oct 2015)(<u>38 U.S.C. 4212</u>). X (30) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793). (31) <u>52.222-37</u>, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212). (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). X (33)(i) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O. 13627).
- \_\_ (ii) Alternate I (Mar 2015) of <u>52.222-50</u> (<u>22 U.S.C. chapter 78</u> and E.O. 13627).
- \_\_ (34) <u>52.222-54</u>, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in <u>22.1803</u>.)
- \_\_ (35) <u>52.222-59</u>, Compliance with Labor Laws (Executive Order 13673) (Oct 2016). (Applies at \$50 million for solicitations and resultant contracts issued from October 25, 2016 through April 24, 2017; applies at \$500,000 for solicitations and resultant contracts issued after April 24, 2017).

**Note to paragraph (b)(35)**: By a court order issued on October 24, 2016, 52.222-59 is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, GSA, DoD and NASA will publish a document in the *Federal Register* advising the public of the termination of the injunction.

- \_\_ (36) <u>52.222-60</u>, Paycheck Transparency (Executive Order 13673) (OCT 2016).
- \_\_ (37)(i) <u>52.223-9</u>, Estimate of Percentage of Recovered Material Content for EPA—Designated Items (May 2008) (<u>42 U.S.C. 6962(c)(3)(A)(ii)</u>). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

- \_\_ (38) <u>52.223-11</u>, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
- \_\_ (39) <u>52.223-12</u>, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
- (40)(i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
- \_\_ (ii) Alternate I (Oct 2015) of <u>52.223-13</u>.
- (41)(i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
- \_\_ (ii) Alternate I (Jun 2014) of 52.223-14.
- \_\_\_(42) <u>52.223-15</u>, Energy Efficiency in Energy-Consuming Products (Dec 2007) (<u>42 U.S.C.</u> 8259b).
- \_\_\_ (43)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
- \_\_ (ii) Alternate I (Jun 2014) of <u>52.223-16</u>.
- $\underline{X}$  (44)  $\underline{52.223-18}$ , Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011) (E.O. 13513).
- \_\_ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
- \_\_ (46) <u>52.223-21</u>, Foams (Jun 2016) (E.O. 13693).
- \_\_\_ (47)(i) <u>52.224-3</u>, Privacy Training (JAN 2017) (5 U.S.C. 552a).
- \_\_ (ii) Alternate I (JAN 2017) of 52.224-3.
- \_\_(48) <u>52.225-1</u>, Buy American—Supplies (May 2014) (<u>41 U.S.C. chapter 83</u>).
- $\underline{X}$  (49)(i)  $\underline{52.225-3}$ , Buy American—Free Trade Agreements—Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
- \_\_ (ii) Alternate I (May 2014) of <u>52.225-3</u>.
- \_\_ (iii) Alternate II (May 2014) of <u>52.225-3</u>.
- X (iv) Alternate III (May 2014) of 52.225-3.
- \_\_ (50) <u>52.225-5</u>, Trade Agreements (Oct 2016) (<u>19 U.S.C. 2501</u>, *et seq.*, <u>19 U.S.C. 3301</u> note).
- $\underline{X}$  (51)  $\underline{52.225-13}$ , Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- \_\_\_ (52) <u>52.225-26</u>, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; <u>10 U.S.C. 2302 Note</u>).
- \_\_\_ (53) <u>52.226-4</u>, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (<u>42 U.S.C.</u> <u>5150</u>).
- \_\_ (54) <u>52.226-5</u>, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (<u>42 U.S.C. 5150</u>).
- \_\_\_(55) <u>52.232-29</u>, Terms for Financing of Purchases of Commercial Items (Feb 2002) (<u>41 U.S.C. 4505</u>, <u>10 U.S.C. 2307(f)</u>).
- \_\_ (56) <u>52.232-30</u>, Installment Payments for Commercial Items (Jan 2017) (<u>41 U.S.C. 4505</u>, <u>10 U.S.C. 2307(f)</u>).
- $\underline{X}$  (57)  $\underline{52.232-33}$ , Payment by Electronic Funds Transfer—System for Award Management (Jul 2013) ( $\underline{31}$  U.S.C.  $\underline{3332}$ ).
- \_\_\_ (58) <u>52.232-34</u>, Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (<u>31 U.S.C. 3332</u>).
- \_\_ (59) <u>52.232-36</u>, Payment by Third Party (May 2014) (<u>31 U.S.C. 3332</u>).
- \_\_\_ (60) <u>52.239-1</u>, Privacy or Security Safeguards (Aug 1996) (<u>5 U.S.</u>C. 552a).
- (61) <u>52.242-5</u>, Payments to Small Business Subcontractors (Jan 2017)(15 U.S.C. 637(d)(12)).
- \_\_ (62)(i) <u>52.247-64</u>, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and <u>10 U.S.C.</u> 2631).
  - \_ (ii) Alternate I (Apr 2003) of <u>52.247-64</u>.
- (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this

contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- \_\_ (1) <u>52.222-17</u>, Nondisplacement of Qualified Workers (May 2014)(E.O. 13495).
- \_\_ (2) <u>52.222-41</u>, Service Contract Labor Standards (May 2014) (<u>41 U.S.C. chapter 67</u>).
- \_\_ (3) <u>52.222-42</u>, Statement of Equivalent Rates for Federal Hires (May 2014) (<u>29 U.S.C. 206</u> and <u>41 U.S.C. chapter 67</u>).
- \_\_ (4) <u>52.222-43</u>, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) (<u>29 U.S.C. 206</u> and <u>41 U.S.C. chapter 67</u>).
- \_\_ (5) <u>52.222-44</u>, Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (May 2014) (<u>29 U.S.C. 206</u> and <u>41 U.S.C. chapter 67</u>).
- (6) <u>52.222-51</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).
- \_\_\_(7) <u>52.222-53</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).
- \_\_\_ (8) <u>52.222-55</u>, Minimum Wages Under Executive Order 13658 (Dec 2015).
- (9) <u>52.222-62</u>, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
- \_\_ (10) <u>52.226-6</u>, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (<u>42</u> <u>U.S.C. 1792</u>).
- (11) <u>52.237-11</u>, Accepting and Dispensing of \$1 Coin (Sept 2008) (<u>31 U.S.C. 5112(p)(1)</u>). (d) *Comptroller General Examination of Record*. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at <u>52.215-2</u>, Audit and Records—Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR <u>subpart 4.7</u>, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—
- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).
- (ii) <u>52.203-19</u>, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (iii) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (iv) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (I) of FAR clause 52.222-17.
- (v) <u>52.222-21</u>, Prohibition of Segregated Facilities (Apr 2015)
- (vi) <u>52.222-26</u>, Equal Opportunity (Sept 2016) (E.O. 11246).

- (vii) <u>52.222-35</u>, Equal Opportunity for Veterans (Oct 2015) (<u>38 U.S.C. 4212</u>).
- (viii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
- (ix) <u>52.222-37</u>, Employment Reports on Veterans (Feb 2016) (<u>38 U.S.C. 4212</u>)
- (x) <u>52.222-40</u>, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause <u>52.222-40</u>.
- (xi) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67). (xii)
- 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O 13627). Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O 13627).
- (xiii) <u>52.222-51</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
- (xiv) <u>52.222-53</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).
- (xv) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
- (xvi) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
- (xvii) <u>52.222-59</u>, Compliance with Labor Laws (Executive Order 13673) (Oct 2016) (Applies at \$50 million for solicitations and resultant contracts issued from October 25, 2016 through April 24, 2017; applies at \$500,000 for solicitations and resultant contracts issued after April 24, 2017).
- **Note to paragraph (e)(1)(xvii)**: By a court order issued on October 24, 2016, 52.222-59 is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, GSA, DoD and NASA will publish a document in the *Federal Register* advising the public of the termination of the injunction.
- (xviii) 52.222-60, Paycheck Transparency (Executive Order 13673) (Oct 2016)).
- (xix) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xx)(A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
- (B) Alternate I (Jan 2017) of 52.224-3.
- (xxi) <u>52.225-26</u>, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; <u>10 U.S.C. 2302 Note</u>).
- (xxii) <u>52.226-6</u>, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (<u>42 U.S.C. 1792</u>). Flow down required in accordance with paragraph (e) of FAR clause <u>52.226-6</u>. (xxiii) <u>52.247-64</u>, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (<u>46 U.S.C. Appx. 1241(b)</u> and <u>10 U.S.C. 2631</u>). Flow down required in accordance with paragraph (d) of FAR clause <u>52.247-64</u>.
- (2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations. (End of clause)

The Defense Priorities and Allocations System (DPAS) and assigned rating are not applicable to this solicitation notice.

All responsible sources may submit a quote, which if timely received, shall be considered. The quote shall reference solicitation number 17-223-SOL-00061. The quotes are due in person, by postal mail or email to the point of contact listed below on or before April 24, 2017, by 12:00 pm (Central Time in Jefferson, Arkansas) at the Food and Drug Administration, OO/OFBA/OAGS/DAP/FOB, Attn: Regina Williams, 3900 NCTR Road, HFT-320, Jefferson, AR 72079-9502.

For information regarding this solicitation, please contact Regina Williams at (870) 543-7012, fax (870) 543-7990 or email: regina.williams@fda.hhs.gov.